

REMARKS

Claims 36 - 51 remain pending in this application. The applicant gratefully acknowledges the allowance of claims 49 - 51. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 36 - 38, 40-44 and 46 - 48 stand rejected under 35 U.S.C. § 102(e) as anticipated by Kuramoto (U.S. Patent No. 5,395,030). The Examiner stated in support of the rejection that Kuramoto shows an endoscopic stapler having a capsule with a stapling mechanism and a cutter that may be inserted into the large intestine through the anus. The Examiner also stated that Kuramoto discloses an endoscope that is placed inside the capsule and extends through the shaft to the operating handle, which also includes grasping forceps that pull the tissue into the location between the stapler and the anvil.

As stated previously, claim 36 recites a resection apparatus comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" and *"a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue."*

Reacted

The Examiner stated that the grasping forceps of Kuramoto acts to pull tissue into the location between the anvil and the stapler. However, it is respectfully submitted that Kuramoto

shows no grasping forceps that grasp any portion of tissue and clearly show no grasping forceps that draw grasp and draw tissue into a cutting zone adjacent to a suturing assembly as required by claim 1. Specifically, the Examiner cited the description of Fig. 3 of Kuramoto in addition to that in Fig. 27. However, it is respectfully submitted that the embodiment of Fig. 3 is quite different from that of Fig. 27 and that the device of Fig. 3 includes no graspers. Nor would any graspers be useful in this application as the device of Fig. 3 is for use in an open surgical full circle anastomosis procedure wherein the surgeon applies a suture manually via an incision to purse string the severed ends of the large intestine around the tubular shaft 23. (Specification, col. 8, lines 30 - 40 and Fig. 3B). Thus, the tissue is drawn between the anvil 6 and the stapling member 4 of this embodiment manually by the purse string suturing.

In addition, the device shown in Fig. 27 includes holding forceps 150 used only to manipulate and hold the tip of an anvil shaft. (Specification, col. 17, lines 39-41). The anvil of this embodiment is removable from the stapling member and is positioned on an opposite side of the tissue to be stapled and resected without the use of graspers of any kind. Specifically, as shown in Fig. 23, a main unit 136 is first inserted into the stomach 110 and an auxiliary unit 141 coupled including the anvil 146 is deployed, passed into the duodenum 111 and manipulated until it abuts the diseased tissue. The anvil shaft 147 is then used to pierce the wall of the duodenum 111 and the wall 113 of the stomach 110. The insertion section 142 is then disconnected from the anvil 146 which is left in position on the walls 113 and 114 of the stomach 110 and the duodenum 111, as shown in Fig. 24. (Specification, col. 17, lines 23 - 34). Thereafter, the main unit 136 is positioned near the tip of the anvil shaft 147 and the holding forceps 150 is deployed from the hole 140 (See, Fig. 22) to grasp the anvil shaft 147. The holding forceps are then withdrawn into the hole 140 to draw the anvil shaft 147 thereinto. (Specification, col. 17, lines 35 - 42). Thus, the holding forceps 150 are used only to draw the anvil back into connection with the housing 138 and, as the anvil shaft 147 is then coupled within the hole 140, the holding forceps are no longer deployable to grasp tissue or for any other purpose.

In response to the Applicants Arguments, the Examiner stated that:

the flexible forceps of Kuramoto could easily be directed to grasp a full thickness fold of tissue and pull it into a cutting zone or the space between the stapler and the anvil, even through this is not shown, because as shown in Fig. 25, the forceps could be directed to a position misaligned with the anvil projection 147 and could grasp a fold of tissue with its jaws.

(Office Action, page 4).

However, it is respectfully submitted that, as described above, the holding forceps 150 are deployable only when the anvil 146 remains unconnected to the housing 138. Under these circumstances, there is no cutting zone formed therebetween and predicting the results of the use of the forceps 150 to grasp tissue in a way neither shown, suggested or even contemplated in Kuramoto to pull tissue to which the anvil 146 is connected while the anvil 146 is not connected to the housing 138 is purely speculative and could in no way be said to assist in performing the function of the device of Kuramoto.

Thus, the applicant respectfully submits that Kuramoto neither shows nor suggests a resection apparatus comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" and "*a tissue grabber grasping a full thickness fold of tissue including the selected portion of tissue and drawing the grasped fold of tissue into the cutting zone, wherein the suturing assembly fastens abutting portions of the grasped fold of tissue,*" as recited in claim 36.

It is therefore respectfully submitted that claim 36 is not anticipated by Kuramoto and that this rejection should be withdrawn. Because claims 37, 38 and 40 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Similarly, claim 44 recites a system for resecting tissue where "*a flexible grasping mechanism extending through the sheath for grasping a full thickness fold of tissue including a portion of tissue selected for resectioning and drawing grasped fold of tissue into a space between the stapling mechanism and the anvil.*" It is respectfully submitted that claim 44 is allowable for the same reasons stated above in regard to claim 36. Because claims 46 - 48 depend from and, therefore, include all of the limitations of claim 44, it is respectfully submitted that these claims are also allowable.

Claims 36 - 48 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta (U.S. Patent No. 5,389,098) in view of Sauer (U.S. Patent No. 5,562,694) and Kessel (DE Publication No. 4,006,673). The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone and an internal endoscope. The Examiner further stated that Sauer shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention. Furthermore, the Examiner stated that Kessel discloses forceps with an internal endoscope.

Claim 36 has recites "*a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle.*" Unlike the apparatus of claim 36, Tsuruta shows various rigid surgical instruments which are inserted into body cavities *via incisions made therein*. (Col. 2, lines 44-46). Specifically, Tsuruta states that the disclosed stapling member operates as follows: "A body wall or the like is incised. The stapling member 5 and the insertion section 2 are inserted into the

body cavity through the incision... (Specification, col. 10, lines 7 - 9). "An incision is formed in a body wall such as the abdominal wall. The stapling member 5 and the insertion section 2 are inserted into a body cavity through the incision." (Specification, col. 26, lines 42 - 46). "To insert the stapling member 5 into a body cavity, it is closed and then inserted into the trocar 314." (Specification, col. 33, lines 28 - 30). It is respectfully submitted therefore that no such flexible member extending "*through the body and out a natural body orifice to the control handle,*" as recited in claim 36 is shown or suggested by Tsuruta.

Furthermore, it is respectfully submitted that Tsuruta not only does not describe any graspers grasping tissue in conjunction with its many embodiments, it specifically states that its stapler allows surgeons "to gather tissues a and b, *without using forceps.*" (Specification, col. 22, lines 20 - 22). That is, the staples themselves are used to draw portions of tissue together so that separate forceps are not needed. (See, specification, col. 23, lines 14 - 29). Tsuruta discloses forceps only for grasping thread guiding needles 225. (Specification, col. 27, lines 29 - 36). Thus, it is respectfully submitted that Tsuruta teaches away from any modification which would add such a grasper to its device as it has been designed to eliminate the need for the device.

Although the Examiner stated that Tsuruta discloses a flexible endoscopic stapler, (col. 34, lines 6-15), Tsuruta merely states that "the insertion section of the stapler can be either rigid or flexible" without disclosing any further details of the construction of the device. (col. 34, lines 6-7). A simple statement that an insertion section of a device including drive mechanisms for various mechanisms (stapler, anvil/stapler moving mechanisms, etc.) may be either flexible or rigid is insufficient disclosure to enable one of skill in the art to make such a device operable and flexible. For example, Tsuruta does not disclose the flexible support structure and the mechanisms involved in transmitting manipulations by the user of the stapler from the control handle to the stapler along a flexible instrument - and certainly does not teach or suggest the structure necessary to arrive at a solution which would enable the device to be flexible enough to travel through a body lumen from a naturally occurring body orifice as required in claim 36. It is respectfully submitted that, since Tsuruta fails to sufficiently disclose a flexible instrument, this

reference is insufficient to support the rejection.

Similarly, Sauer shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is locatable entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a flexible endoscope. Specifically, Sauer states that endoscopic procedures involve "incising through body walls for examining, viewing and/or operating on various bodily organs or structures" with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is not flexible as that term is used in this application and includes no "flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle," as recited in claim 36. Thus, it is respectfully submitted that both Tsuruta and Sauer are designed for use in conjunction with open surgery and are unsuitable to extend "through the body and out a natural body orifice to the control handle," as recited in claim 36

The Examiner cites Kessel since it discloses forceps with an internal endoscope. That reference, however, has no relevance to surgical stapling and also shows a body lumen being accessed via an incision. Thus, it is respectfully submitted that Kessel fails to cure the above-noted deficiencies in Tsuruta and Sauer.

For these reasons, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either show or suggest an apparatus for resecting tissue within a body lumen, comprising "an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting

zone adjacent to the suturing assembly" in combination with "a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle" as recited in claim 36.

It is therefore respectfully submitted that claim 36 is not rendered obvious by Tsuruta, Sauer and Kessel either taken alone or in combination and that this rejection should be withdrawn. Because claims 37 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Similarly, claim 44 recites "*an operating head including a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained, wherein the anvil and the stapling mechanism are permanently coupled to one another," in combination with "*a flexible grasping mechanism extending through the sheath for drawing tissue into a space between the stapling mechanism and the anvil.*"

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta, Sauer, nor Kessel either shows or suggests a system including "*a flexible endoscope*" and "*an operating head including a coupling structure for selectively coupling to the endoscope,*" as recited in claim 44.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

It is respectfully submitted that all of the presently pending claims are allowable and that the present application is in condition for allowance. Therefore, a prompt and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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